



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 15, 2020

OPP Decision Number: D-558920

Keeva Shultz
Sharda Cropchem Ltd.
c/o Wagner Regulatory Associates, Inc.
P.O. Box 640
Hockessin, DE 19707

Subject: Data Deficiency
Product Name: Sharda Thiamethoxam Technical
EPA File Symbol: 82633-UG
Application Date: December 31, 2019
EPA Receipt Date: December 31, 2019

Dear Ms. Shultz:

The Agency has received and begun its in-depth review of the subject application and has determined that it is incomplete or that further information is needed. This letter is a written notification of those deficiencies and identifies your options under 40 CFR 152.105 and Section 33 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended by the Pesticide Registration Improvement Extension Act (PRIA 3). Your options under 40 CFR 152.105 and section 33 of FIFRA are addressed separately because each involves a different timeframe and set of options for responding to this letter. Please ensure that you consider each of the sections below in determining how and when you respond to this letter.

40 CFR 152.105:

Pursuant to 40 CFR 152.105, you are allowed 75 days from the date of this letter ending **March 1, 2021** to provide a response concerning the deficiencies listed in this letter. Your response may include making corrections or additions to complete the application or notifying the Agency of the date on which you expect to complete the application or withdrawing your application. If you do not respond to this letter within 75 days or if you respond with a date on which you expect to complete the application but fail to meet that scheduled date, the Agency will treat the application as if you had withdrawn it. Withdrawal concludes the Agency's review of your application. Any subsequent submission of the same application must then be submitted as a new application with a new deadline for EPA to make a determination on your application and subject to a new registration service fee.

The deficiencies identified in the Agency's review at this time are as follows:

- Data for Guideline 830.6314 (Oxidation/reduction: chemical incompatibility) are required. The waiver request based only on its physical state was not acceptable.
- The product data submitted for Guidelines 830.7200, 830.7550, 830.7840 and 830.7950 (melting point, partition coefficient, water solubility and vapor pressure) need to be generated from a batch of material with an analyzed purity of 99.4% or higher.
- The product data submitted for Guideline 830.6317 (storage stability) tested in glass bottles was found to be acceptable. However, the tested container was not made of the commercial packaging material that is listed on the label (e.g., plastic, lined fiber drums and supersack bags).
- The product data submitted for 830.6320 (corrosion characteristics) was found to be acceptable for aluminum, zinc, copper and polyethylene sheets. However, the containers tested do not support some of the commercial packaging listed on the label.

Further review of your application and your response to the deficiencies may identify additional deficiencies and you will be so informed.

FIFRA Section 33/PRIA:

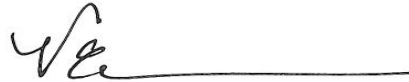
This application is also subject to a deadline for making a determination on the application under FIFRA Section 33, Pesticide Registration Service Fees, established under PRIA. The time frame for the Agency to make a determination on this application ends on **December 23, 2020**. Because the deadline for the agency to make a determination on this application expires before the end of the 75 days you have to respond to the deficiencies noted above, you have the following three options:

1. **Establish a new due date.** You may work with us to establish a new section 33/PRIA deadline that allows for an appropriate response to the 75-day letter. If you choose this option, you need to contact the Agency not later than **December 17, 2020** to discuss a time frame that allows you to address the deficiencies listed above and the Agency to make a regulatory decision.
2. **Withdraw the application.** Alternatively, you may notify us not later than **December 17, 2020** that you are withdrawing your application. **As noted above, withdrawal concludes the Agency's review** of your application; however, you may resubmit your application after the deficiencies have been addressed. Should you choose to resubmit your application, it would be subject to a new deadline for making a determination on your application and a new registration service fee. Since a fee was paid with this application, the Agency will provide any applicable refund as soon as practicable.

3. **Not respond.** If the Agency does not hear from you by **December 17, 2020**, the Agency in meeting its obligations under section 33/PRIA may issue a determination to not grant your application. While a determination to not grant an application would allow EPA to have met its obligation under section 33 of FIFRA to issue a determination by a specified date, this determination is neither a denial of the application pursuant to section 3(c)(6) of FIFRA or a withdrawal of the application. Thus, the Agency will continue to diligently work on any such application as long as EPA receives a response to a deficiency notice within the 75 days described above.

Please respond to this letter by **December 17, 2020** by contacting Kevin Ulrich by phone at 703-347-0464, or via email at ulrich.kevin@epa.gov with a response and for any questions concerning this letter. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

A handwritten signature in dark ink, appearing to read 'Venus Eagle', followed by a horizontal line.

Venus Eagle, Product Manager 01
Invertebrate and Vertebrate Branch 3
Registration Division (7505P)
Office of Pesticide Programs